

NOT FOR PUBLICATION

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

Treace Medical Concepts Incorporated,

Plaintiff,

v.

Fusion Orthopedics LLC,

Defendant.

No. CV-22-00490-PHX-SRB

ORDER

The Court now considers Plaintiff Treace Medical Concepts, Inc.’s (“Treace”) Motion for Preliminary Injunction (“Motion”). (Doc. 58 (“Mot.”).) The Court will deny the Motion.

I. BACKGROUND

Treace and Defendant Fusion Orthopedics, LLC (“Fusion”) are competitors in the hallux valgus (“bunion”) surgery market. A bunion is a deformation of the first metatarsal and medial cuneiform that creates a bump on the side of the big toe. (Doc. 34, Am. Compl. ¶¶ 11, 13.) Traditional bunion surgery shaves and cuts the relevant foot bones to improve appearance but does not address the underlying bone deformity. (*Id.* ¶ 12.) In response to traditional surgery, Treace released LapiPlasty 3D Bunion Correction (“LapiPlasty”) in 2015 to realign the first metatarsal and medial cuneiform. (*Id.* ¶ 13; Mot. at 3.) Fusion later debuted LapiLock 4D Correction Surgery (“LapiLock”), which realigns the first metatarsal and medial cuneiform. (Am. Compl. ¶ 41.) Both procedures originally involved, *inter alia*, (1) placing a fulcrum between the first and second

1 metatarsal before correcting the intermetatarsal angle and (2) using a cut block to cut the
2 metatarsal and medial cuneiform before securing the corrected joint. (*See* Mot. at 4; Doc.
3 58-1, Ex. 10, LapiLock 4D Bunion Correction Surgical Technique (“Surgical Guide
4 Version I”) at 6–10.)

5 On February 16, 2022, Treace sent Fusion a cease-and-desist letter claiming that
6 LapiLock infringed on several of Treace’s patents due in part to Fusion’s use of fulcrums,
7 cut blocks, and joint seekers. (Am. Compl. ¶ 32.) After receiving Treace’s cease-and-
8 desist letter, Fusion modified the published description of LapiLock to specify that its
9 “fulcrum” was only a “spacer,”¹ which the surgeon should remove before “correct[ing]
10 the intermetatarsal angle.” (Mot. at 6; Doc. 58-1, Ex. 11, (“LapiLock Video Version I”);
11 Doc. 58-2, Ex. 12 (“Surgical Guide Version II”) at 6, 8.) On March 28, 2022, Fusion
12 started advertising LapiLock as “fulcrum-less” and claimed it was superior to LapiPlasty.
13 (Doc. 58-2, Ex. 13, Fusion 03/28/2022 Press Release (“March Press Release”) at 2.)
14 Unsatisfied with Fusion’s responses, Treace filed its Complaint on March 29, 2022
15 alleging ten causes of action against Fusion, including false advertising. (*See generally*
16 Doc. 1, Compl.)

17 In April 2022, Fusion began recalling the Instruments, cut blocks, and joint
18 seekers. (Doc. 77, Resp. to Mot. (“Resp.”) at 3.) Fusion then released a LapiLock
19 promotional video and product brochure that omitted the Instrument and explicit
20 references to bone cutting. (*See* Doc. 58-2, Ex. 16, (“LapiLock Video Version II”); Doc.
21 58-4, Ex. 17, (“LapiLock Brochure”) at 2.) On August 24, 2022 Fusion put out a press
22 release advertising LapiLock as “fulcrum-less.” (Ex. 14, Fusion 08/24/2022 Press
23 Release (“August Press Release”) at 2–3.) Fusion then released a new surgical guide that
24 omitted the Instrument but explained the bone-cutting process. (*See* Doc. 77-6, Ex. 13,
25 (“Surgical Guide Version III”).)

26 Treace filed this Motion on September 2, 2022, requesting that the Court enjoin
27 Fusion from falsely advertising that LapiLock is “fulcrum-less” and does not require
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¹ Fulcrum and spacer are hereinafter referred to generally as “Instrument.”

bone cutting. (Mot. at 1–2.) Fusion subsequently updated its LapiLock video to expressly describe the bone-cutting process but continued to omit the Instrument. (Reply at 2.) Fusion responded to the Motion on September 23, 2022, to which Treace filed its Reply on September 30, 2022. (Resp.; Reply.) The Court heard oral argument on the Motion on October 25, 2022. (Doc. 106, Min. Entry.)

II. LEGAL STANDARD & ANALYSIS

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Id.* at 20 (citations omitted). All four elements must be satisfied, and the movant bears the burden of proof on each element. *hiQ Labs, Inc. v. LinkedIn Corp.*, 938 F.3d 985, 992 (9th Cir. 2019), *vacated on other grounds*, 141 S. Ct. 2752 (2021). The Ninth Circuit employs a “sliding scale” approach to these elements, in which “a stronger showing of one element may offset a weaker showing of another.” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). Under this approach, “serious questions going to the merits” can also support an injunction if “the balance of hardships tips sharply in the plaintiff’s favor” and the plaintiff satisfies the two remaining *Winters* factors. *Id.* at 1135. “Serious questions” are questions that are “substantial, difficult, and doubtful, as to make them fair ground for litigation and thus for more deliberative investigation.” *Iconix, Inc. v. Tokuda*, 457 F. Supp. 2d 969, 975 (N.D. Cal. 2006) (citation omitted).

A. Likelihood of Success on the Merits

Section 43(a) of the Lanham Act provides for the civil liability of any person who, “in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities.” 15 U.S.C. § 1125(a). To succeed on a Lanham Act false advertising claim, a plaintiff must prove:

(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by lessening of the goodwill associated with its products.

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997).

“To demonstrate falsity within the meaning of the Lanham Act, a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers.” *Id.* “In analyzing whether an advertisement . . . is literally false, a court must determine, first, the unambiguous claims made by the advertisement . . . and second, whether those claims are false.” *In-N-Out Burgers v. Smashburger IP Holder LLC*, No. SACV 17-1474 JVS(DFMx), 2019 WL 1431904, at *4 (C.D. Cal. Feb. 6, 2019) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms, Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). The court must analyze the advertisement “in its full context” to determine whether it is literally false. *Southland Sod Farms*, 108 F.3d at 1139.

Treace argues that Fusion falsely advertised that LapiLock does not involve bone cutting and continues to falsely advertise that LapiLock is a “fulcrum-less” procedure. (Mot. at 8–11.) Fusion counters that its LapiLock materials have always accurately reflected the various changes it made to the LapiLock procedure after receiving Treace’s cease-and-desist letter. (Resp. at 3–5.) The Court finds that Treace has not met its burden to warrant a preliminary injunction against Fusion’s advertising.

1. LapiLock’s Bone Cutting Steps

Treace claims that Fusion’s omission of bone-cutting steps in its April 2022 LapiLock video and brochure is literally false by necessary implication. (Mot. at 10; *see* LapiLock Video Version II; LapiLock Brochure.) To find an advertisement false by necessary implication, the court analyzes the claim in its entirety to determine whether the “audience would recognize the false implied claim as easily as if it had been stated

explicitly.” *FLIR Sys., Inc. v. Sierra Media, Inc.*, 903 F. Supp. 2d 1120, 1129 (D. Or. 2012); *CertainTeed Corp. v. Seattle Roof Brokers*, No. C09-563RAJ, 2010 WL 2640083, at *10 (W.D. Wash. June 28, 2010) (“A statement is literally false by implication if, read in context, it unambiguously conveys a literally false message.”). A message is less likely to be literally false the more that the “message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion.” *eMove Inc. v. SMD Software Inc.*, No. CV-10-02052-PHX-JRG, 2012 WL 1379063, at *4 (D. Ariz. Apr. 20, 2012) (citing *Novartis*, 290 F.3d at 586–87).

After beginning to recall its cut blocks and joint seekers, Fusion released its April 2022 updated LapiLock video that removed reference to these devices but informed the viewer that the surgeon may “distract the joint to remove the articular surface” before securing the joint. (*Compare* LapiLock Video Version I, at 3:00–:55 *with* LapiLock Video Version II, at 2:45–3:10.) Fusion’s LapiLock brochure explained LapiLock in four steps, which included “compress[ing] the unstable joint for improved fusion.” (LapiLock Brochure at 2.) Moreover, Fusion’s press releases explained that LapiLock involves “[m]inimal bone resection² to better maintain first metatarsal length.” (March Press Release; August Press Release.) Though these statements may have been ambiguous, Fusion’s audience would have recognized that LapiLock involves some method to “resect” and fuse the joint. An audience would also see that Fusion was providing simplified information about LapiLock instead of describing the full procedure. (*See* LapiLock Video Version II at 04:21 (stating the video was “for general informational and educational purpose [and] not the complete surgical technique.”).)

When considered in their full context, Fusion’s statements about joint preparation and fusion were at most ambiguous and did not necessarily imply that LapiLock does not require bone cutting. *See Novartis*, 290 F.3d at 587 (“[O]nly an unambiguous message can be literally false.”); *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 275–76 (4th Cir. 2002) (an advertisement that “can reasonably be understood as conveying different

² “Resection” is “the surgical removal of part of an organ or structure.” *Resection*, MERRIAM-WEBSTER DICTIONARY (11th ed. 2003).

1 messages” is not literally false.). Most importantly, Treace acknowledges that Fusion
 2 now explicitly explains LapiLock’s bone-cutting steps in its current LapiLock video.
 3 (Doc. 126, Transcript of Motion Hearing (“Transcript”) at 8:1–3.) Treace has not shown a
 4 likelihood of success on or questions going to the merits of a false advertising claim as to
 5 Fusion’s former alleged omission of bone cutting steps.

6 **2. LapiLock’s Use of a “Fulcrum”**

7 Fusion has released several iterations of LapiLock since it received Treace’s
 8 cease-and-desist letter in February 2022. In early March 2022, Fusion adjusted the
 9 advertising for LapiLock to clarify that the Instrument was a “spacer.” (Mot. at 6; Am.
 10 Compl. ¶¶ 36–37.) According to Fusion, “fulcrum” was a misnomer because LapiLock
 11 used the Instrument only for spacing and not as a “hinge” to correct the intermetatarsal
 12 angle. (Doc. 77-4, Ex. 8, Jacobson Decl. at ¶¶ 16–17 (the LapiLock “jig” acts as the pivot
 13 point); LapiLock Video Version I, at 02:07 (instructing surgeon to remove the Instrument
 14 before intermetatarsal correction); Surgical Guide Version II, at 6 (same)); *see Fulcrum*,
 15 MERRIAM-WEBSTER DICTIONARY (11th ed. 2003) (a “prop” or “support about which a
 16 lever turns”). Treace does not address Fusion’s argument that the Instrument was used as
 17 a spacer and not a fulcrum but contends that any use or distribution of the Instrument
 18 rendered Fusion’s press releases false. (Mot. at 8; Reply at 4; Transcript at 16:11–17:1.)
 19 Treace’s bare assertion is insufficient to prove that Fusion’s press releases describing
 20 LapiLock as “fulcrum-less” are literally false for purposes of this Motion.

21 Treace has also failed to prove that Fusion’s omission of the Instrument in its
 22 videos, surgical guides, and brochure render these materials literally false.³ Fusion
 23 contends that it has discontinued the use of the Instrument in LapiLock surgeries and
 24 substantially completed its recall by August 8, 2022. (Resp. at 3, 12.) Fusion has removed

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 26 ³ Treace asks the Court to demand that Fusion provide proof that LapiLock no longer
 27 uses the Instrument because Treace believes that “Fusion is being untruthful” and Treace
 28 is not certain that LapiLock is “fulcrum-less.” (Mot. at 3, 8; Transcript at 30:5–9.) But
 Treace has the burden of proving literal falsity and has not demonstrated that LapiLock
 surgeries continue to use the Instrument. *See Southland Sod Farms*, 108 F.3d at 1139; *U-
 Haul Intern., Inc. v. Jartran, Inc.*, 522 F. Supp. 1238, 1248 (D. Ariz. 1981) (defendant is
 not required to “prove the truth of its asserted product claims.”).

1 the Instrument from its LapiLock video and surgical guide. (*See* LapiLock Video Version
 2 II; Surgical Guide Version III.) Treace contends that a packing slip shows that Fusion
 3 was shipping Instruments in early July, but Treace’s evidence does not support this
 4 argument. (Reply at 5.) This packing slip merely indicates that Fusion transferred some
 5 Instruments from Fusion’s “Offsite Inven[tory] to “Fusion Inventory.” (Doc. 84-1, Ex.
 6 34, Packing Slip.) Treace has not shown a likelihood of success on or serious questions
 7 going to the merits of a false advertising claim as to whether LapiLock is currently a
 8 “fulcrum-less” procedure.⁴

9 **B. Remaining *Winters* Factors**

10 Because Treace has not shown that it is likely to succeed on or raised serious
 11 questions going to its false advertising claim, the Court need not consider the remaining
 12 *Winters* factors. *See All. for the Wild Rockies*, 632 F.3d at 1135 (movant must establish
 13 all four elements). The Court denies the Motion.⁵

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22 ⁴ Treace makes much of 45 Instruments that purportedly remained in circulation as of
 23 September 2022. Treace has not shown that surgeons are using these 45
 24 “[unlocated]/lost/destroyed” Instruments or that Fusion continues to supply Instruments
 25 in its current LapiLock trays. (*See* Doc. 84-1, Ex. 35, LapiLock Order & Recall
 26 Summary.) After learning that Treace found a LapiLock tray in July 2022 containing
 27 three Instruments, Fusion recalled *all* LapiLock “inventory” to confirm that there were no
 28 other unrecovered Instruments in circulation. (Resp. at 4; Doc. 77-2, Ex. 4, Distributor
 Termination Letter; Doc. 115, Ex. 5, Distributor Recall Letter.) Moreover, any alleged
 use of these Instruments after Fusion’s recall relates to Treace’s infringement claims, not
 to the truthfulness of Fusion’s advertising about its current LapiLock procedure.

⁵ On September 23, 2022, Fusion filed a Motion to Strike the declaration of Jeffrey
 McAlister in support of Treace’s Motion. (*See* Doc. 77, Mot. to Strike Expert
 Testimony.) The Motion to Strike is denied as moot.

